



## Proposed Regulation Agency Background Document

<b>Agency name</b>	Board of Dentistry, Department of Health Professions
<b>Virginia Administrative Code (VAC) citation</b>	18 VAC 60-20
<b>Regulation title</b>	Regulations Governing the Practice of Dentistry and Dental Hygiene
<b>Action title</b>	Requirements for administration of analgesia and local anesthesia by dental hygienists
<b>Document preparation date</b>	3/20/07

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

### Brief summary

*In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.*

The Board is proposing to amend regulations to comply with a statutory mandate as set forth in Chapter 858 of the 2006 Acts of the Assembly. In its proposed regulatory action, the Board is establishing the education and examination required for a dental hygienist to demonstrate competency in the administration of local anesthesia and nitrous oxide under the direction of a licensed dentist, including a minimum of 8 didactic and clinical hours for administration of nitrous oxide and 36 hours for administration of both nitrous and local anesthesia.

### Legal basis

*Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.*

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Dentistry the authority to promulgate regulations to administer the regulatory system:

**§ 54.1-2400 -General powers and duties of health regulatory boards**

*The general powers and duties of health regulatory boards shall be:*

...

*6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ [54.1-100](#) et seq.) and Chapter 25 (§ [54.1-2500](#) et seq.) of this title. ...*

The Dental Practice Act (Chapter 27 of Title 54.1) was amended by Chapter 858 of the 2006 Acts of the Assembly (<http://leg1.state.va.us/cgi-bin/legp504.exe?061+ful+CHAP0858>) as follows: “A dentist may also authorize a dental hygienist under his direction to administer Schedule VI nitrous oxide and oxygen inhalation analgesia and, to persons 18 years of age or older, Schedule VI local anesthesia. In its regulations, the Board of Dentistry shall establish the education and training requirements for dental hygienists to administer such controlled substances under a dentist's direction.”

Therefore, the Board of Dentistry has a statutory mandate to establish education and training requirements for hygienists to administer.

## Purpose

*Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal and the problems the proposal is intended to solve.*

Chapter 858 of the 2006 Acts of the Assembly mandates the promulgation of regulations establishing the qualifications or credentials necessary for a dental hygienist to administer inhalation analgesia/nitrous oxide and local anesthesia. In the development of regulations, the Board looked at certification requirements in other states and considered a curriculum recommended by the VCU School of Dentistry. The didactic hours in an accredited program coupled with a requirement for clinical experiences with patients and passage of an examination will ensure that a licensed hygienist will have the minimal competency to provide the expanded services with safety. In addition, the law and regulation require that administration must be under the dentist’s direction (defined as meaning that “the dentist examines the patient and is present for observation, advice, and control over the performance of dental services”). Hygienists who are licensed by endorsement from other states can be qualified for administration, if their education and training was substantially equivalent to requirements of this chapter, or if not, by demonstrating years of experience in administration of nitrous or local anesthesia. Expansion of the scope of practice for dental hygienists should make these services more available to the citizens of the Commonwealth and should support appropriate dental care.

## Substance

*Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the "Detail of changes" section.)*

The Board is mandated to promulgate regulations establishing the qualifications necessary for a dental hygienist to administer *Schedule VI nitrous oxide and oxygen inhalation analgesia and, to persons 18 years of age or older, Schedule VI local anesthesia*. Such qualifications include specific hours of didactic and clinical training, demonstration of clinical skills on patients, and testing of competency.

The law permits administration of nitrous oxide and local anesthesia by a dental hygienist if authorized by a dentist and only under his direction. "Direction" is already defined in regulations of the Board as "the dentist examines the patient and is present for observation, advice, and control over the performance of dental services," so regulations are specific about the level of supervision required for such administration.

In addition to establishing requirements for the education and training of dental hygienists, the Board has amended existing regulations for the administration of inhalation analgesia and the listing of non-delegable duties, consistent with the amended law. Current regulations for administration and monitoring by dentists are appropriately amended to allow hygienists qualified by education and training to also administer and monitor under the same provisions necessary to protect the health and safety of dental patients.

## Issues

*Please identify the issues associated with the proposed regulatory action, including:*

- 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
- 2) the primary advantages and disadvantages to the agency or the Commonwealth; and*
- 3) other pertinent matters of interest to the regulated community, government officials, and the public.*

*If the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.*

1) The primary advantage of the proposed regulation to the public would be the expanded practice of dental hygienists who would be able to see more patients and provide additional services that require local anesthesia or administration of nitrous oxide. With the additional education and examination of such hygienists, the public could be assured that they possess credentialing indicating minimal competency. In addition, the law and regulation require that the supervising dentist be present and provide direction for the administration by a hygienist. The current requirements for monitoring and safety equipment are applicable regardless of which practitioner provides the administration. There should be no disadvantages to the public.

2) There are no specific advantages or disadvantages to the agency or the Commonwealth. Agencies of the Commonwealth that provide dental services may find it possible to expand those

services to certain populations with the use of hygienists who are qualified to administer local anesthesia and nitrous.

3) There are no other issues or pertinent matters.

**Economic impact**

*Please identify the anticipated economic impact of the proposed regulation.*

<p><b>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures</b></p>	<p>a) As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners for necessary functions of regulation; b) The agency will incur some one-time costs (less than \$1,000) for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending notice of final regulations to regulated entities. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled. There are no on-going costs to the agency.</p>
<p><b>Projected cost of the regulation on localities</b></p>	<p>There are none.</p>
<p><b>Description of the individuals, businesses or other entities likely to be affected by the regulation</b></p>	<p>The individuals that may be affected by the regulation are dental hygienists who will qualify for administration of analgesia inhalation and/or local anesthesia. The dentists who employ those hygienists will also be affected.</p>
<p><b>Agency’s best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected.</b> Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>There are 5890 licensed dentists and 4307 dental hygienists. The number of persons who may seek to qualify for administration of nitrous and anesthesia is unknown. Since hygienists are employees of dentists, the number who would be considered as small businesses would be the dentists who employ hygienists who hold the required credential.</p>
<p><b>All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.</b></p>	<p>There is no requirement that anyone who is licensed as a hygienist or a dentist comply with the proposed regulations. Compliance is voluntary for those who want to expand their current scope of practice to provide additional services for patients and be able to charge for those services. The costs for a combined course for hygienists in the administration of anesthesia and nitrous is estimated by the VCU School of Dentistry is estimated at \$1,000 for 36 hours over 4.5 days with an enrollment of 20 students per class. The ability of a hygienist to administer such drugs would likely</p>

	expand the practice and enhance the earning capacity for the hygienist and the dentist for whom he works, well in excess of the cost for completion of a qualifying program.
--	--

**Alternatives**

*Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action.*

---

According to the American Dental Hygienists’ Association, there are laws and/or regulations permitting dental hygienists to administer local anesthesia in 38 other states. To implement Chapter 858, the Board has reviewed educational and training requirements in other states – particularly states in this region of the country. At present, Kentucky, Tennessee, West Virginia and South Carolina have provisions similar to those in Virginia relating to administration of local anesthesia by hygienists.

In a review of requirements from other states, the Board found wide variation in the training and in the practice. The lowest number of hours of education was found in Kansas (12) with the highest number found in Louisiana (72). Following a recommendation of the Virginia Dental Association, the Board reviewed Kentucky regulations as a model for Virginia regulation because they appeared to be reasonable and balanced in the combination of didactic and clinical experiences and the passage of a qualifying examination.

In Kentucky, regulations require certification to administer infiltration anesthesia and nitrous oxide under the delegation and direct supervision of a dentist. To be eligible for a certificate granted by the Board, hygienists must complete 32 hours of course work in pharmacology, technique, evaluation, complications and contraindications from a dental or hygiene program accredited by the ADA. To demonstrate clinical skills, they also have to complete at least 2 hours in clinical education in administration of nitrous oxide and demonstrate proficiency on at least 2 patients and a minimum of 12 hours in mastery of local anesthesia application with 3 injections in each of the sites. Finally, they have to pass a written examination administered after the coursework and clinical training.

The Board will recognize anesthesia education from other states if the instruction and course content requirements are equal to or greater than those in Virginia. Tennessee and South Carolina also issue local infiltration anesthesia certifications after successful completion of a board-approved certification course located in dental schools or community colleges; South Carolina only allows dental hygienist to monitor nitrous oxide rather than administer. North Carolina does not permit hygienists to administer nitrous or local anesthesia. If a hygienist is licensed by endorsement from another state and was qualified in that state by education and training that is not substantially equivalent, he may be qualified in Virginia by documenting experience in administration for 24 out of the past 48 months.

There was discussion about requiring hygienists to submit their education, training and examination credentials to the Board for approval, but that alternative was not accepted because

there is no statutory authority for the Board to issue a certificate or to charge a fee for review of credentials. The dentist who employs the hygienist has the responsibility for assuring that he/she has met the requirements of the regulation and is legally administering the drugs.

The Board also considered a requirement for posting a certificate issued by the educational program in the operatory where the public is receiving the services. Since the certificate would not be issued by the Board, its posting would not necessarily convey evidence of minimal competency to the general public.

Other alternatives that were not included in the regulation were: 1) a requirement for passage of an examination offered by one of the regional testing companies (WREB has an examination but others do not yet offer one); 2) a requirement for continuing education (current CPR certification is required but there is no CE specified for administration of nitrous or local anesthesia); and 3) a requirement for dentists to teach the clinical portion of the course (hygiene instructors in dental hygiene programs may be well qualified to provide instruction in the clinical experiences).

**Public comment**

*Please summarize all comments received during public comment period following the publication of the NOIRA, and provide the agency response.*

A Notice of Intended Regulatory Action was published on August 7, 2006 with comment accepted until September 6, 2007. The following comment was received during that period:

<b>Commenter</b>	<b>Comment</b>	<b>Agency response</b>
Cheryl Todd, RDH	Recommended 24 hours of education in the administration of local anesthesia as adequate. Also suggested no limitation on the patient's age or the procedure to be performed.	The Board considered hours of education from other states as well as a draft curriculum developed by the VCU School of Dentistry. That course has 23 hours of didactic coursework with clinical hours and testing hours totally 36, so the proposed regulation is consistent with the request from the commenter. The law specifies that local anesthesia can only be administered to patients 18 years of age or older, so the regulations cannot be in conflict with the law.
Melanie Bartlam, RDH	Provided a summary of the 2005 VDA/VDHA/VDAA Task Force Committee on local anesthesia and nitrous oxide	The course recommended in 2005 contained 32 hours of instruction and clinical experience but did not include hours for a written examination, which the VCU draft curriculum does include.

In addition to comment received during the NOIRA comment period, the Regulatory/Legislative Committee and the Board received comment/suggestions/input from the Virginia Dental Hygienists Association, the Virginia Dental Association and other interested parties at each meeting at which the regulations were discussed.

**Family impact**

*Please assess the impact of the proposed regulatory action on the institution of the family and family stability.*

There is no impact of the regulatory action on the institution of the family and family stability.

**Detail of changes**

*Please detail all changes that are being proposed and the consequences of the proposed changes. Detail all new provisions and/or all changes to existing sections.*

*If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.*

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
n/a	81	n/a	<p>Section 81. Sets out the requirements for administration local anesthesia and/or nitrous oxide by dental hygienists.</p> <p>Subsection A states the parameters for administration within the limitations of the law. It states that a dental hygienist who meets the qualifications set forth in this section and who is under the direction of a dentist may administer nitrous oxide/inhalation analgesia or, to patients 18 years of age or older, local anesthesia. It also clarifies that “local anesthesia” does not include topical Schedule VI medicinal agents which may be administered under general supervision pursuant to 18VAC60-220 B.</p> <p><i>The regulation is consistent with amendments to 54.1-2722 and 54.1-3408 of the Code of Virginia.</i></p> <p>Subsection B sets out the eligibility requirements for administration of only nitrous oxide/inhalation analgesia. Those requirements include:</p> <ol style="list-style-type: none"> <li>1. Successfully completion of a didactic and clinical course leading to certification in administration of nitrous oxide offered by a dental or dental hygiene program accredited by the Commission on Dental Accreditation of the American Dental Association, which includes a minimum of 8 didactic and clinical hours in the following topics:               <ol style="list-style-type: none"> <li>a. Patient physical and psychological assessment;</li> <li>b. Medical history evaluation;</li> <li>c. Equipment and techniques used for administration of nitrous oxide;</li> <li>d. Neurophysiology of nitrous oxide administration;</li> </ol> </li> </ol>

		<p>e. Pharmacology of nitrous oxide;  f. Record keeping, medical and legal aspects of nitrous oxide;  g. Adjunctive uses of nitrous oxide for dental patients; and  h. Clinical experiences in administering nitrous oxide, including training with live patients.  and  2. Successfully completion of an examination with a minimum score of 75% in the administration of nitrous oxide/inhalation analgesia given by the accredited program.</p> <p>Subsection C sets out the eligibility requirements for administration of <i>both local anesthesia and nitrous oxide/inhalation analgesia</i> to include:  1. Successfully completion of a didactic and clinical course leading to certification in administration of local anesthesia and nitrous oxide/inhalation analgesia which is offered by a dental or dental hygiene program accredited by the Commission on Dental Accreditation of the American Dental Association, which includes a minimum of <b>36</b> didactic and clinical hours in the following topics:  a. Patient physical and psychological assessment;  b. Medical history evaluation and record keeping;  c. Neurophysiology of local anesthesia;  d. Pharmacology of local anesthetics and vasoconstrictors;  e. Anatomical considerations for local anesthesia;  f. Techniques for maxillary infiltration and block anesthesia;  g. Techniques for mandibular infiltration and block anesthesia;  h. Local and systemic anesthetic complications;  i. Management of medical emergencies;  j. Clinical experiences in maxillary and mandibular infiltration and block injections;  k. Pharmacology of nitrous oxide;  l. Adjunctive uses of nitrous oxide for dental patients; and  m. Clinical experiences in administering nitrous oxide and local anesthesia injections on patients.  and  2. Successfully completion of an examination with a minimum score of 75% in the administration of nitrous oxide/inhalation analgesia and local anesthesia given by the accredited program.</p> <p><i>The course content is consistent with recommendations made by the Dean of the VCU School of Dentistry and the Director of the Dental Hygiene Program. It includes the subjects that must be covered to ensure minimal competency. The Board will not be approving programs, so to ensure quality and consistency in the offering of nitrous and local anesthesia courses, the Board determined that programs must be accredited. In addition, each program must include clinical experiences using live patients to indicate an ability to safely perform the tasks and a qualifying examination to demonstrate knowledge in</i></p>
--	--	---

			<p><i>the delivery of such drugs.</i></p> <p>Subsection D sets out the requirements for administration of nitrous oxide/inhalation analgesia or local anesthesia by a dental hygienist who holds a certificate or credential issued by the licensing board of another U. S. jurisdiction. They may be authorized for such administration in Virginia if:</p> <ol style="list-style-type: none"> <li>1. The qualifications on which the credential or certificate was issued were substantially equivalent in hours of instruction and course content to those set forth in subsections B and C; or</li> <li>2. If the certificate or credential issued by another jurisdiction was not substantially equivalent, the hygienist can document experience in such administration for at least 24 of the past 48 months preceding application for licensure in Virginia.</li> </ol> <p><i>Since the requirements for administration vary from state to state, the Board has included experience as a means of demonstrating competency to administer.</i></p> <p>Subsection E states that a dentist who provides direction for the administration of nitrous oxide/inhalation analgesia or local anesthesia must ensure that the dental hygienist has met the qualifications for such administration as set forth in this section.</p> <p><i>Since there is no certification from the Board and credentials will not be reviewed by the Board, it remains the responsibility of the dentist to ensure the qualifications have been met.</i></p>
108	n/a	Sets out the general requirements for administration of anxiolysis or inhalation analgesia.	<p>Subsection B states the equipment requirements and provides that a dentist who utilizes anxiolysis or inhalation analgesia shall maintain the specified equipment in his office and be trained in its use. The amended regulation adds “or who directs the administration of inhalation analgesia by a dental hygienist.”</p> <p><i>Since a dental hygienist must be employed by and work under the direction of a dentist, it must be the responsibility of the dentist to ensure that the necessary safety equipment is available in the office for the administration of nitrous oxide.</i></p> <p>Subsection C sets out the monitoring requirements for anxiolysis or inhalation analgesia. <i>Amendments are adopted to distinguish between anxiolysis (which only dentists can administer) and inhalation analgesia (which both dentists and qualified hygienists can administer).</i></p>
190	n/a	Sets out the duties that cannot be delegated by a dentists to a dental hygienist.	<p>With the change in the law, the administration of nitrous oxide or oxygen inhalation analgesia can no longer be a non-delegable duty. It may be delegated to a hygienist who meets the qualification set out in section 81.</p>

220	n/a	Sets out the duties of a dental hygienist under direction with the dentist present or under general supervision,	<p>Subsection A sets out the duties that can only be delegated to dental hygienists under direction with the dentist being present. To that list, the Board has added: “Administering nitrous oxide or local anesthesia by eligible dental hygienists in accordance with the requirements of 18VAC60-20-81. “</p> <p><i>The requirement for administration of nitrous or local anesthesia under direction (with the dentist present and available) is consistent with the provisions of the Code.</i></p>
-----	-----	--	---